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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,648	03/30/2001	David G. Lowe	P1819R1	8510

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EXAMINER
CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 01/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/823,648	Marsters
Examiner	**Art Unit**
Arun Chakrabarti	1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- *Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.*
- *If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.*
- *If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.*
- *Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).*
- *Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).*

Status

1) ☒ *Responsive to communication(s) filed on 2/30/01, 4/19/01, 5/31/01, 8/6/01, 9/20/01, 11/02/01, 12/20/01 .*

2a) ☐ *This action is* **FINAL.** 2b) ☒ *This action is non-final.*

3) ☐ *Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.*

Disposition of Claims

4) ☒ *Claim(s) 1-40 is/are pending in the application.*

4a) *Of the above, claim(s) _____ is/are withdrawn from consideration.*

5) ☐ *Claim(s) _____ is/are allowed.*

6) ☒ *Claim(s) 1-40 is/are rejected.*

7) ☐ *Claim(s) _____ is/are objected to.*

8) ☐ *Claims _____ are subject to restriction and/or election requirement.*

Application Papers

9) ☐ *The specification is objected to by the Examiner.*

10) ☐ *The drawing(s) filed on _____ is/are objected to by the Examiner.*

11) ☐ *The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.*

12) ☐ *The oath or declaration is objected to by the Examiner.*

Priority under 35 U.S.C. § 119

13) ☐ *Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).*

a) ☐ *All* b) ☐ *Some** c) ☐ *None of:*

1. ☐ *Certified copies of the priority documents have been received.*
2. ☐ *Certified copies of the priority documents have been received in Application No. _____ .*
3. ☐ *Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).*

**See the attached detailed Office action for a list of the certified copies not received.*

14) ☐ *Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).*

Attachment(s)

15) ☒ *Notice of References Cited (PTO-892)*

16) ☐ *Notice of Draftsperson's Patent Drawing Review (PTO-948)*

17) ☒ *Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7, 9*

18) ☐ *Interview Summary (PTO-413) Paper No(s). _____*

19) ☐ *Notice of Informal Patent Application (PTO-152)*

20) ☐ *Other:*

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, claims 1-40 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that there is no burden in examining the claims of Groups I I-V. This is not found persuasive because as the restriction makes clear, additional search of Groups II-V would require review not only of the 1500 patents in class 536, subclass 22.1 for Group I, but also the 204 patents in class 502, subclass 180 for Group II, 803 patents in class 585, subclass 906 for Group III, 1189 patents in class 536, subclass 25.3 for Group IV and also 12627 patents in class 435, subclass 6 for Group V. Review of these additional searches is prima facie evidence of burden which is not rebutted.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 17, and 25-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 17, the phrase "and like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "and like"), thereby rendering the scope of the claim(s) unascertainable.

Regarding claim 25, the phrase "capable of" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1-9, 15-19, 25-27, and 40 are rejected under 35 U.S.C. 102 (a) as being anticipated by Thompson et al. (PCT International Publication Number WO 99/20640) (April 29, 1999).

Thompson et al teach a microarray comprising a surface sialinized with a silane in toluene in the absence of acetone or an alcohol, and a target molecule, wherein the target molecule is attached to the surface via the silane (Abstract, page 17a, line 18 to page 19, line 31, and page 30, line 11 to page 31, line 10 and Claim 1).

Thompson et al teach a microarray comprising a linker, wherein the target molecule is attached to the surface via the linker (Abstract, Claims 3-4 and 11-14 and page 1, lines 11-15 and page 2, line 25 to page 3, line 24).

Thompson et al teach a microarray, wherein the target is a DNA polynucleotide ranging from 3 bp to 10 Kb (Abstract, Claim 10, and page 30, line 11 to page 32, line 15 and page 8, line 32 to page 9, line 25).

Thompson et al teach a microarray, wherein the planar substrate surface is selected from polymeric materials, ceramics, glasses, or glass slides, plates or electrophoretic membranes (Claim 12 and Figures 2-3).

Thompson et al teach a microarray prepared by a method comprising:

a) providing a multifunctional linker reagent comprising two or more reactive groups capable of reacting with a functional group on a surface of a microarray substrate and capable of reacting with a target molecule (Abstract, Claims 1-11, and page 8, line 20 to page 9, line 6);

b) activating the substrate surface for immobilizing the target molecule, by silanizing the surface with a silane in toluene in the absence of acetone or an alcohol, wherein the silane comprises a functionally reactive molecule with the multifunctional linker reagent , and wherein the activating further comprises immobilizing the multifunctional linker reagent on the silanized surface by attaching the multifunctional linker reagent to the silane via a first reactive group of the linker reagent and a reactive group of the silane (Abstract, Claims 1-11 and page 9, line 8 to page 11, line 19 and page 17a, line 30 to page 18, line 19);

c) providing a solution comprising a target having one or more functional groups reactive with a second reactive group of the immobilized multifunctional linker reagent (page 11, line 20 to page 13, line 29 and claim 17);

d) attaching the target molecule to the substrate surface by contacting the target molecule with the activated substrate surface under conditions that promote attachment of the target molecule to the immobilized multifunctional linker reagent (page 13, line 30 to page 15, line 26 and Abstract and Claim 18).

Thompson et al teach a microarray, wherein the target molecule is an unmodified polynucleotide, and wherein the contacting of step (d) is carried out by spotting the polynucleotide on an activated substrate surface (Abstract, figure 3 and 5, and page 43, line 13 to page 46, line 14).

Thompson et al teach a microarray, wherein the microarray further comprises, after step (d), blocking unreacted reactive groups (Claim 16 and page 15, lines 14-16).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-9, 15-19, 25-27, and 30-40 are rejected under 35 U.S.C. 103 (a) over Thompson et al. (PCT International Publication Number WO 99/20640) (April 29, 1999).

Thompson et al teach a microarray of claims 1-9, 15-19, 25-27 and 40 as described above.

Thompson et al do not teach the concentration of the polynucleotide spot in the range of 0.1 microgram/microliter to 3 microgram/microliter, and the pH range of attaching step (d) is from 6 to 10 and attaching is allowed from 1-24 hours.

However, it is *prima facie* obvious that selection of the specific polynucleotide spotting concentration, pH range and incubation time for the attaching reaction represents routine optimization with regard to production of desired microarray which routine optimization parameters are explicitly recognized to an ordinary practitioner in the relevant art. As noted *In re Aller*, 105 USPQ 233 at 235,

> More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable

ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the specific polynucleotide spotting concentration, pH range and incubation time for the attaching reaction selection performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

8. Claims 1-19, and 25-40 are rejected under 35 U.S.C. 103 (a) over Thompson et al. (PCT International Publication Number WO 99/20640) (April 29, 1999) in view of Dintzis et al. (U.S. Patent 6,340,460 B1) (January 22, 2002).

Thompson et al teach a microarray of claims 1-9, 15-19, 25-27, and 30-40 as described above.

Thompson et al do not teach a microarray comprising a primary amine at the 5' end of the polynucleotide, wherein the primary amine is attached at the 5' end of the polynucleotide via a linker, wherein the linker comprises one or more monomers of 1-20 carbon atoms, and wherein the monomer comprises a linear chain of carbon or rings.

Dintzis et al. teach a microarray comprising a primary amine at the 5' end of the polynucleotide, wherein the primary amine is attached at the 5' end of the polynucleotide via a linker, wherein the linker comprises one or more monomers of 1-20 carbon atoms, and wherein

the monomer comprises a linear chain of carbon or rings (Column 15, lines 5-16 and Column 37, lines 48-58).

Thompson et al do not teach a microarray, wherein the polynucleotide is prepared by extending a nucleic acid primer comprising a primary amine at its 5' end.

Dintzis et al. teach a microarray, wherein the polynucleotide is prepared by extending a nucleic acid primer comprising a primary amine at its 5' end (Column 15, lines 5-16 and Column 37, lines 48-58).

It would have been *prima facie* obvious to an ordinary practitioner to combine and substitute a microarray, comprising a primary amine at the 5' end of the polynucleotide, wherein the primary amine is attached at the 5' end of the polynucleotide via a linker, wherein the linker comprises one or more monomers of 1-20 carbon atoms, and wherein the monomer comprises a linear chain of carbon or rings as taught by Dintzis et al. in the microarray of Thompson et al., since Dintzis et al. state, "For general conjugation reactions, introduction of, for example, primary amines onto the scaffold provides a functional group capable of accepting multiple chemical modifications or manipulations that can be achieved using mild conditions in aqueous solutions (Column 15, lines 5-9)." Moreover, Dintzis et al provides further motivation as Dintzis et al state, "As an alternative to the Aminolink approach, this method (of amine incorporation) has the advantage of verification of incorporation of the nucleotide bearing the protected amino group (via standard DNA calorimetric coupling assays) (Column 37, lines 54-58)". An ordinary practitioner would have been motivated to combine and substitute a microarray, comprising a

primary amine at the 5' end of the polynucleotide, wherein the primary amine is attached at the 5' end of the polynucleotide via a linker, wherein the linker comprises one or more monomers of 1-20 carbon atoms, and wherein the monomer comprises a linear chain of carbon or rings as taught by Dintzis et al. in the microarray of Thompson et al. in order to achieve the express advantages, as noted by Dintzis et al. of introduction of primary amines onto the scaffold which provides a functional group capable of accepting multiple chemical modifications or manipulations that can be achieved using mild conditions in aqueous solutions and also to achieve the advantage of verification of incorporation of the nucleotide bearing the protected amino group (via standard DNA calorimetric coupling assays).

9. Claims 1-9, 15-21, 25-27, and 30-40 are rejected under 35 U.S.C. 103 (a) over Thompson et al. (PCT International Publication Number WO 99/20640) (April 29, 1999) in view of Friend et al. (U.S. Patent 6,324,479 B1) (November 27, 2001).

Thompson et al teach a microarray of claims 1-9, 15-19, 25-27, and 30-40 as described above.

Thompson et al do not teach a microarray, wherein the unmodified target molecule is attached after contacting the target molecule with the surface by a technique selected from printing or deposition on mask.

Friend et al. teach a microarray, wherein the unmodified target molecule is attached after contacting the target molecule with the surface by a technique selected from printing or deposition on mask (Column 34, lines 9-67).

It would have been *prima facie* obvious to an ordinary practitioner to combine and substitute a microarray, wherein the unmodified target molecule is attached after contacting the target molecule with the surface by a technique selected from printing or deposition on mask as taught by Friend et al. in the microarray of Thompson et al., since Friend et al. state, "A preferred method for attaching the nucleic acids to a surface is by printing on glass plates. This method is especially useful for preparing microarrays of cDNA (Column 34, lines 13-17)." An ordinary practitioner would have been motivated to combine and substitute a microarray, wherein the unmodified target molecule is attached after contacting the target molecule with the surface by a technique selected from printing or deposition on mask as taught by Friend et al. in the microarray of Thompson et al. in order to achieve the express advantages, as noted by Friend et al., of a preferred method for attaching the nucleic acids to a surface by printing on glass plates which is especially useful for preparing microarrays of cDNA.

10. Claims 1-19, and 22-40 are rejected under 35 U.S.C. 103 (a) over Thompson et al. (PCT International Publication Number WO 99/20640) (April 29, 1999) in view of Dintzis et al. (U.S. Patent 6,340,460 B1) (January 22, 2002) further in view of Friend et al. (U.S. Patent 6,324,479 B1) (November 27, 2001).

Thompson et al. in view of Dintzis et al teach the microarray of claims 1-19, and 25-40 as described above including the modification of target nucleotide with primary amine.

Thompson et al. in view of Dintzis et al do not teach a microarray, wherein the unmodified target molecule is attached after contacting the target molecule with the surface by a technique selected from printing or deposition on mask.

Friend et al. teach a microarray, wherein the unmodified target molecule is attached after contacting the target molecule with the surface by a technique selected from printing or deposition on mask (Column 34, lines 9-67).

It would have been *prima facie* obvious to an ordinary practitioner to combine and substitute a microarray, wherein the unmodified target molecule is attached after contacting the target molecule with the surface by a technique selected from printing or deposition on mask as taught by Friend et al. in the microarray of Thompson et al in view of Dintzis et al., since Friend et al. state, "A preferred method for attaching the nucleic acids to a surface is by printing on glass plates. This method is especially useful for preparing microarrays of cDNA (Column 34, lines 13-17)." An ordinary practitioner would have been motivated to combine and substitute a microarray, wherein the unmodified target molecule is attached after contacting the target molecule with the surface by a technique selected from printing or deposition on mask as taught by Friend et al. in the microarray of Thompson et al. in view of Dintzis et al in order to achieve the express advantages, as noted by Friend et al., of a preferred method for attaching the nucleic acids to a surface by printing on glass plates which is especially useful for preparing microarrays of cDNA.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti , Ph. D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding

should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Arun kr. Chakrabarti

Arun Chakrabarti,

Patent Examiner

January 22, 2002